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EXAMINER	
HOFFMAN, MARY C	

ART UNIT	PAPER NUMBER
3733	

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/762,008	GROB ET AL.	
	Examiner	Art Unit	
	Mary Hoffman	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-37 is/are pending in the application.

4a) Of the above claim(s) 25-37 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-24 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 21 January 2004 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 6/27/05, 11/26/04, 4/01/04, 11/26/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-24, drawn to a cervical facet resurfacing apparatus, classified in class 623, subclass 17.11.

II. Claims 25-37, drawn to method for providing articulating surfaces, classified in class 606, subclass 61.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can be implanted using a guide, or the articulating surfaces for the implant can be formed using a surgical tool other than a rasp.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mark C. Johnson on January 30, 2006, a provisional election was made without traverse to prosecute the invention of I, claims 1-24. Affirmation of this election must be made by applicant in replying to this Office action. Claims 25-37 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

The abstract of the disclosure is objected to because it contains phrases that can be implied, i.e. "the present invention relates". Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The

disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: ref. # 200. Furthermore, the tool of FIG. 11 is not labeled, and there are inconsistencies, such as ref. # 104 is used in both FIG. 5A and FIG. 10, denoting different items, and ref. # 804 in the specification, page 14, lines 24, is described in the specification as "shaft 804", however, it is used in the FIG. 8 to denote a method step. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "at least on ridge

oriented in a different direction than the other regions" of claim 13 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 5 and 9 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claim 5 and 9, applicant positively recites part of a human,

i.e. "wherein the tab is attached to the lateral mass of the selected vertebra". Thus claims 5 and 9 include a human within their scope and are non-statutory. The suggested change is --wherein the tab is configured to be attached to the lateral mass of the selected vertebra--.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7-9, 11-13, 15, 18 and 20-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Gill et al. (U.S. Patent No. 6,113,637).

Gill et al. disclose a cervical facet resurfacing implant (FIG. 1a, ref. #20) comprising a superior implant (FIG. 1a, ref. #22) having an articulating surface and a fixation surface capable of secured placement on a resurfaced superior articulating facet of a selected cervical vertebra, and an inferior implant (FIG. 1a, ref. #24) having an articulating surface and a fixation surface and capable of secured placement on a resurfaced inferior articulating facet of a cervical articulating immediately above the

selected cervical articulating such that the articulating surface of the inferior implant interacts with the articulating surface of the superior implant. The superior implant and inferior implant are each generally disk-shaped. A tab (FIG. 1, ref. #34) extends from the generally disk-shaped portion of the superior implant. The tab is capable of attaching to the lateral mass of the selected cervical vertebra. The tab is capable of being attached to the lateral mass of the selected cervical vertebra with a screw. The inferior implant further comprises a tab (FIG. 1, ref. #56) extending from the generally disk-shaped portion of the inferior implant. The cervical facet resurfacing implant is capable of attaching to the inferior articular process of the cervical vertebra immediately above the selected cervical vertebra. The tab is capable of being attached to the inferior articulating process of the cervical vertebra immediately above the selected cervical vertebra with a screw. A least one of the superior implant and the inferior implant comprises a surface fixation mechanism (FIG. 2, ref. #36). The surface fixation mechanism comprises a screw hole. The surface fixation mechanism comprises multiple regions and wherein each of the regions has at least one ridge oriented in a different direction than the other regions (see outside ridges of circular hole ref. #36). The articulating surface of at least one of the inferior implant and the superior implant is composed of any known biomaterial, which includes cobalt-chromium alloy, ceramic, UHMWPE, pyrolytic carbon, and Ti/AIN. The cervical facet resurfacing implant further comprising a trans-lateral mass fixation mechanism capable of securing the inferior implant to the inferior articular facet (FIG. 1, ref. #30).

Claims 1, 3-5, 11-13, 15 and18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Martin (U.S. Patent No. 6,132,464).

Martin discloses a cervical facet resurfacing implant (see FIG. 7)comprising a superior implant (FIG. 7, ref. #7) having an articulating surface and a fixation surface capable of secured placement on a resurfaced superior articulating facet of a selected cervical vertebra, and an inferior implant (FIG. 7, ref. #2) having an articulating surface and a fixation surface and capable of secured placement on a resurfaced inferior articulating facet of a cervical articulating immediately above the selected cervical articulating such that the articulating surface of the inferior implant interacts with the articulating surface of the superior implant. A tab (FIG. 1, ref. #19) extends from the superior implant. The tab is capable of attaching to the lateral mass of the selected cervical vertebra. The tab is capable of being attached to the lateral mass of the selected cervical vertebra with a screw. The cervical facet resurfacing implant is capable of attaching to the inferior articular process of the cervical vertebra immediately above the selected cervical vertebra. The tab is capable of being attached to the inferior articulating process of the cervical vertebra immediately above the selected cervical vertebra with a screw. A least one of the superior implant and the inferior implant comprises a surface fixation mechanism (FIG. 2, ref. #18). The surface fixation mechanism comprises a screw hole (FIG. 2, ref. #18). The surface fixation mechanism comprises multiple regions and wherein each of the regions has at least one ridge oriented in a different direction than the other regions (see outside ridges of circular hole ref. #18). The articulating surface of at least one of the inferior implant and the superior

implant is composed of a metallic alloy, with Ti/AlN being an example of a metallic alloy (col. 1, lines 59-end). The cervical facet resurfacing implant further comprising a trans-lateral mass fixation mechanism (FIG. 7, ref. #17) capable of securing the inferior implant to the inferior articular facet. The trans-lateral mass fixation mechanism comprises at a translaminar screw (FIG. 7, ref. #17).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6, 10, 14 and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gill et al. (U.S. Patent No. 6,113,637) in view of Fitz (U.S. Patent No. 5,571,191).

Gill et al. disclose the claimed invention except for the fixation surface of at least one of the inferior implant and the superior implant having at least one of: a porous coating, a porous onlay material, a biologic coating, a surface treatment, and a material facilitating ingrowth of bone.

Fitz discloses using a porous coating to allow for bony ingrowth to occur and firmly attach implant components to the bone.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Gill et al. with a porous coating in view of

Fitz in order to allow for bony ingrowth to occur and firmly attach implant components to the bone.

With regard to claims 6, 10, and 16-17, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of the combination of Gill et al. with the tab and the disk-shaped portion of the superior implant forming an angle of from about 110 degrees to about 160 degrees, the tab and the disk-shaped portion of the inferior implant form an angle of from about 10 degrees to about 70 degrees, the inferior implant and superior implant each range from about 1 mm thick to about 6 mm thick, and the inferior implant and superior implant each range from about 3 mm in diameter to about 14 mm in diameter, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please see attached PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MCH

EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER